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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/086,138	05/28/98	JAFFE R	ETLIP002US

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EXAMINER	
GITOMER,R	
ART UNIT	**PAPER NUMBER**
1623	12

DATE MAILED: 02/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/086,138	Jaffe
Examiner	**Group Art Unit**
Ralph Gitomer	1623

☒ Responsive to communication(s) filed on *Jan 31, 1900*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-15* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-15* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The arguments and Declaration received 1/31/0 have been entered and claims 1-15 are currently pending in this application. In view of the kind and helpful comments presented, new rejections follow and the previous rejection under 35 USC 101 is hereby withdrawn. This Office action is made final.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,387,508. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of `508 do not include nor exclude any dilution or concentration of the sample prior to testing.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaffe.

Jaffe (5,387,508) by the present inventor entitled "Detection of Cytotoxic Agents Using Tetramitus Rostratus" teaches in ~~claim~~ column 3 first paragraph, the sample may be a liquid, gaseous or solid material. Various types of whole effluent samples are taught.

It is noted the present specification on page 2 last paragraph discusses '508 where '508 does not disclose a WET test in which all of the potentially toxic substances from the sample are evaluated in a natural combination. See in '508 Example 5 in column 6 where a WET sample is tested. See the claims.

The claims differ from Jaffe in that they recite other flagellates than those taught by Jaffe.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ flagellates other than T. Rostratus because in view of the teachings of Jaffe, one would have a high expectation of success in employing any known flagellate with the requisite qualities taught in the present specification. It is noted that the present specification teaches specific methods and examples only for T rostratus.

Further, the present claims recite the sample is combined with the culture directly.

In `508 column 3 first paragraph, ▒samples may be concentrated, or, in the case of solids, suspended in a liquid, prior to testing.▒ It would appear the sensitivity of the test would be dependent upon the concentration of the cytotoxic substances and to dilute or concentrate samples to make them more suitable for a given test is well known in this art and taught by `508, see column 7 Table 2.

Applicant's arguments filed 1/31/00 have been fully considered but they are not persuasive.

Applicant argues that the present claims require the whole effluent sample is combined directly with the culture which means there is no requirement for concentration of the sample prior to combining it with the culture. Examples 5 and 6 of Jaffe are not WET tests because a toxic substance is added to the sample. To

suggest that Jaffe teaches concentration of the sample is optional does not extrapolate to a WET test. Only hindsight in view of Jaffe would teach a WET test. Jaffe does not teach any flagellates other than T. rostratus. The limitations of claims 7 and 11 have not been addressed. A Declaration by the inventor is presented which states the EPA definition of WET test and Examples 5 of Jaffe is not a WET test because it was contrived to evaluate the flagellates adaptation and immunity abilities.

It is the examiner's position that the specification and claims of `508 consider the feature of concentrating the sample optional, see discussion presented above. In example 5 of Jaffe, the sample is fumes from a rubber stamp manufacturer and no concentration of the fumes is recited. Jaffe teaches conclusions of the results of Example 5 as ▒An inexpensive identification procedure would then be possible prior to costly qualitative/quantitative analyses.▒ This would appear to mean the test was contrived to be an effective analysis.

It is noted in present claim 1(a) the step is ▒obtaining a sample for testing suspected of containing a plurality of potentially cytotoxic substances▒ is not limited to any particular type of sample. For example, the sample could be a concentrated sample which would accomplish the function stated in the preamble. No other limitations are presented regarding the type of sample or its concentration in the claims. Therefore,

the present claims read on a concentrated sample as taught by Jaffe. The present specification teaches in page 9 for example, various dilutions of sample are required to obtain the desired information which includes both dilution and concentration.

Applicants are reminded that the invention is the subject matter defined by the claims, and the limitations of the specification are not read into the claims where no express statement of that limitation is included in the claims, see In re Priest, 199 USPQ 11.

The Applicants remarks with regard to the Examiner's use of improper hindsight have been noted but the reference clearly shows the claims rendered obvious for reasons discussed above. The fact that the Applicants have selected specific teachings from this reference is still deemed obvious. At the time this invention was made the teachings of the reference was clearly in the public domain and one of ordinary skill in this art knowing of this reference could have selected as the Applicants have done.

Regarding the selection of a specific flagellate, the present specification appears to enabling for T. rostratus. See the present specification on page 4 second paragraph which is confusing regarding the question mark in line 12 and suggesting Tetramitus is unsuitable for marine water samples but none are taught. No advantage of any other flagellate is specifically

taught and an undisclosed advantage is given little or no weight. All the functions of the present claims are taught by the present specification for only T. rostratus.

Regarding the limitations of claim 7 directed to filtering (which reads on concentrating), and claim 11 directed to particulates, Jaffe teaches concentrating particulates in column 7 Example 8, and filtering is a known method of concentrating particulates. It would appear applicants are masking the invention at hand by focusing on obvious and irrelevant subject matter.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on (703) 308-1701. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234.

Ralph Gitomer
Primary Examiner
Group 1623

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200